

Human Subjects Research Database (HSRD)

HSRD status 2006

- Number of human subjects
 - Total human subjects – 970K (ORNL 59%, NIOSH 14%)
- Funding for human subjects research
 - Total Federal funding - \$112 M
 - Total DOE funding - \$78 M (NAS 18%, QC 15%)
- Number of projects
 - Total active projects – 290 (LBNL, LLNL, MIND, BNL, LANL)
- Types of research
 - Human subjects involvement – Epi 48%, clinical 14%
- Facilities – Total 47 (12 DOE, 35 other)

Recent enhancements to database

- 2005: Addition of data on progress and status of research current fiscal year
- 2006: ID of international projects
- 2006: Clarifications
 - Project start date is IRB approval date
 - Only Federal funding sources reported
- 2007: ID of vulnerable populations

Promotional materials

- 2006 Annual Report
 - Number of human subjects increased in greatly in 1999, peaked in 2002, and steadily decreased since
 - Total Federal funding increased except 2000 and 2003
 - Trend in DOE funding tracks total funding
 - Upward trend since 2000 in projects in upper funding ranges
 - Total, active, and active DOE projects generally increased at moderate rate since 1997
- HSRD Brochure - Provides background and basis for HSRD
- DOE Poster – Quick reference material for HSRD

Regulations and DOE Orders

- Federal Rule 45 CFR Part 46 *Protection of Human Subjects* (4 subparts)
 - Pregnant women, fetuses, children, prisoners
- Federal Rule 45 CFR Part 46 Subpart A
“Common Rule”
 - Pregnant women, fetuses, children, prisoners
- DOE reg 10 CFR Part 745 *Protection of Human Subjects* (includes only Subpart A of 45 CFR 46)
 - Pregnant women, fetuses, children, prisoners

Regulations and DOE Orders (cont'd)

- DOE Orders

- 443.1 (2000) Policy on the Protection of Human Subjects *Research involving pregnant or lactating women, children, prisoners, or the mentally disabled must be conducted in accordance with 45 CFR Part 46 Subparts B, C, and D.*
- 481.1 (2005) Work for Others

Vulnerable populations

- Defined by regulation
 - 45 CFR 46
 - Pregnant women and fetuses
 - Children
 - Prisoners
- Under investigation by working group of SACHRP
 - Cognitively impaired (substance abusers, while impaired)
 - Addressing separate section to rule for impaired group
- Section 45 CFR 46.113 (a3)
 - Deliberate IRB review of certain populations

Vulnerable populations (cont'd)

- 45 CFR 46.113 (a3)
 - Risks minimized
 - Sound research design
 - No unnecessary exposure to risk
 - Use procedures for diagnostic and treatment purposes
 - Risks reasonable wrt anticipated benefits and knowledge gained
 - Evaluate risks and benefits related only to research
 - IRB not to consider possible long-term effects of research
 - Subject selection equitable
 - Purpose(s) of the research
 - Setting in which research conducted
 - Special problems of vulnerable populations
 - Children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons

Vulnerable populations (cont'd)

- Potential inclusion of additional groups:
 - Drug users because temporarily cognitively impaired
 - Those with HIV infection and AIDS
 - Homosexual individuals
 - Necessary additional considerations
 - Type and purpose of research
 - Will risk be greater than if not homosexual and participating in study
 - If so, how?
 - Any possible remedial or mitigating measures

Vulnerable populations in HSRD

- Children
- Prisoners
- Pregnant women
- Mentally impaired persons or mentally disabled persons
- Educationally, socially, or economically disadvantaged persons
- DOE workers (including contractors)
- Other, please specify

Vulnerable populations at sites

BNL	esedp (11), mipmdp (3), DOE workers, children (2), other
BSU	children
CUHSC	DOE workers
DU	DOE workers
INL	DOE workers (4)
LANL	DOE workers (2)
LLNL	children (7), DOE workers (2), other (2)
MCW	DOE workers
MIND	mipmdp (7), children (2), prisoners (2)
NAS	children, pregnant women
ORAU	children (6), DOE workers (13)
ORNL	mipmdp
SNL	DOE workers (6), other
UCSF	children, pregnant women
ULRF	children
WASU	DOE workers, other

Questions

- 45 CFR 46 Subpart B, C, D
 - Not formally adopted by DOE
 - Subparts B, C, and D now included in revised DOE order
 - Sites now use Subparts B, C, D and DHHS guidance
 - Should DOE officially endorse these subparts?
- From sites
 - Should former DOE workers still be vulnerable due to legacy issues from prior exposures?
 - What about de-identified data from current workers?
- General
 - Any new categories to add to study status choices in Item #12?